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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,044	01/19/2007	Koji Sode	3691-0132PUS1	7577
2292 7590 07/29/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER WILDER, CYNTHIA B	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 07/29/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/580,044	Applicant(s) SODE ET AL.	
	Examiner CYNTHIA B. WILDER	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/2008/ 11/3/2006/ 9/29/2006/ 5/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-9 with traverse in the reply filed on 5/6/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly the claims 10-19 are withdrawn from consideration as being drawn to a non-elected invention. The Examiner acknowledges Applicant's comments concerning rejoinder of the non-elected subject matter if the elected invention is deemed allowable.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/19/2008 has been considered by Examiner. However, the reference CD (Kazunon Ikebukuro et al) was not considered because Applicant did not provide a publication date for the reference cited therein. No publication date could be established by the Examiner.

Claim Objections

3. Claims 6 and 7 are objected to because of the following informalities: The claims 6 and 7 are objected to because the limitations recited therein do not further limit the structure of the aptamer-probe complex of the claim 1 from which they depend. The limitations of the claims 6 and 7 recite "intended properties" of the aptamer probe complex when the complex is bound to a target. The

Art Unit: 1637

limitations do not further define or modify the structure of the aptamer -probe complex as claimed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-9 are indefinite in the claim 1 for the recitation of the "wherein clause". The claims are confusing because they are drawn to a product and not a method. A product does not perform any actual method steps and there are no limitations within the claims which requires a specific element being bound to another specific element.. In this case, there are no limitations which require the presence of an indicator protein or an indicator protein being bound to the aptamer. Likewise, there are no limitations which require that a target be bound to the probe moiety. Thus, it cannot be clearly determined what conditions are required for the aptamer moiety and probe moiety to combined and further it is unclear how the indicator protein effects the binding of the probe to the aptamer in the complex. Clarification is required.

Claim Interpretation

6. The as currently written are extremely broad and vague as discussed above. The claims 1 and 9 comprise "intended use" limitations that do not define the structure or function of the aptamer-probe complex. Such limitations as "for

Art Unit: 1637

detecting the presence of a target molecule"; "which is able to bind to an indicator protein" and "which is able to bind to a target molecule" are all intended use limitations of the complex that do not carry any patentable weight. Accordingly, for the purpose of application of prior art, the claims are being interpreted by the Examiner as a complex comprising an aptamer and probe or alternatively, an aptamer comprising an indicator protein and probe. With regards to claims 6 and 7, the limitations do not further limit the structure of the complex and only recite properties of the complex that are based on the action of the complex in a reaction. Given the ambiguity of the claim, the limitations are being interpreted as an inherent property of the aptamer-probe complex in the presence of an indicator protein.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3-7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by King (US 20050176940, June 2002). Regarding claims 1-7 and 9, King teaches an aptamer comprising an oligonucleotide sequence capable of binding to a target molecule and a binding region capable of binding to an

Art Unit: 1637

indicator protein wherein said indicator protein is thrombin. King teaches wherein the oligonucleotide (probe) comprises RNA or DNA and further wherein the target is a protein or other molecule. The binding properties of the indicator protein are deemed inherent in the teaching of the aptamer/oligonucleotide complex (see paragraphs 0072-0074 and 0077-0080). Therefore, King meets the limitations of the claims as currently written.

9. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al (20050089864, January 2003). Regarding claims 1-7 and 9, Li et al teaches an aptamer-probe complex comprising a probe moiety and aptamer moiety and a signalling moiety (see paragraphs 0009-0019, 0031-0036). Li et al teach wherein the target molecule can be small molecules, nucleotides, amino acids, peptides, macromolecules such as proteins and nucleic acid and even entire organisms (0002). Li et al teach wherein indicator protein may be thrombin (0017). The binding properties of the indicator protein are deemed inherent in the teachings of the aptamer/oligonucleotide complex (see pages 2-4). Therefore, Li et al meets the limitations of the claims as currently written.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1637

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al (6680377, effective filing date May 14, 1999). Regarding claims 1-9, teaches the addition of several different sets of oligonucleotides to the 5' end of a known thrombin aptamer to form a group of bioengineered aptamer beacons that are designed to exhibit alternate, non-binding conformation in a G-quartet structure of the original aptamer (col. 23, Example 2). Stanton teaches that the a fluorescence quenching pair is added to the 5' ends of some of the bioengineered aptamers allowing determination of the aptamer beacon conformation by observing the fluorescence emission (Example 2). Stanton teaches wherein the target may comprise a protein, a steroid and an inorganic molecule (col. 3, lines 56-59) and further teaches wherein the target is Salmonella bacteria (col. 18, 52-53).

Stanton does not expressly teach wherein the target oligonucleotide is bound to the probe oligonucleotide of the complex. However, Stanton teaches

Art Unit: 1637

numerous modifications of aptamer designs including the use of software programs for designing aptamers in order to increase specificity of detection of a desired target (see columns 8-10 and col. 21-22). Stanton teaches that the aptamers can be designed such that the aptamer beacons can be attached to conductive polymers in which binding of a target molecule to the aptamer beacon causes a change in conformation of the aptamer beacon causing a conformation change in the polymer, altering the conductivity (col. 17, lines 4-10). Stanton teaches that the aptamer can be designed such that the aptamer beacon binds to a non-nucleic acid target molecule and includes an oligonucleotide comprising a first segment, a second segment and a third segment and a binding region which binds to a target molecule (see col. 3, lines 13-30 and Figure 4C and D which teaches wherein 40b represents the aptamer, 42b represents the oligonucleotide with a binding region 44b configured to bind to a target molecule 46b). Stanton also teaches that the aptamers can be designed to detect a specific target using a two component system (see Figure 9).

It would have been *prima facie* obvious to one of ordinary skill in the art to have been motivated to modify the aptamer-probe complex or thrombin beacon aptamer complex of Stanton to encompass a multiplicity of structures including those comprising both a thrombin beacon aptamer complex and probe complex for the obvious benefit of increasing specificity of detecting a desired target as suggested by Stanton. One of ordinary skill in the art at the time of the claimed invention could expect a reasonable expectation of success in modifying the aptamer-probe complex of Stanton since such modifications do not

Art Unit: 1637

negatively alter, modify or effect the function of the aptamer-probe complex taught by Stanton.

Conclusion

13. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637